"A STUDY TO ASSESS THE EFFECTIVENESS OF SOYA BEANS ON SOMATIC AND VASOMOTOR SYMPTOMS AMONG MENOPAUSAL WOMEN RESIDING IN SELECTED VILLAGES AT DISTRICT BUDGAM, KASHMIR."

SYNOPSIS

Submitted for the registration of Degree for

Ph.D. in Nursing

Supervisor -Submitted by-

Dr.S.VICTOR — *Suraya Gani*

Professor — *P.hD (NURSING)*

DeshBhagat University — *19RCPHDNU016*

DESH BHAGAT UNIVERSITY MANDI GOBINDGARH PUNJAB.

I am willing to guide the research work of Suraya Gani on the above subject ifshe is registered for Ph.D.

2. To the best of my knowledge the subject selected for research has not been studied and is not being studied so far in any of the University.

3. The Subject is of sufficient scope to keep the candidate engaged for two years.

4. The subject will lead to the valuable contribution in the respective field of knowledge. I have seen and approved the Synopsis and bibliography, etc. submitted by the candidate.

5. Necessary facilities are available in the Department for the above research work (Certificate from Principal/Head University Department with regards to facilities available is enclosed.)

6. I have_____ research candidate registered under my Supervision and the serial number of this candidate whose application being forwarded for registration is _____.

7. The candidate is not in a close relation (the term close relation is defined in the Examination Ordinance of the University).

Supervisor

Dr.S.VICTOR

This is certified that the available facilities will be extended to the candidate for research work if he / she is registered for the Ph.D.

Signature of the Principal/Director
of the Institution with date

Synopsis for registration of topic for Ph.D. Thesis

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2.	*Name Of Faculty /Discipline*	*Ph.d In Nursing (Child Health Nursing)*
3.	*Title Of Research*	*"A STUDY TO ASSESS THE EFFECTIVENESS OF SOYA BEANS ON SOMATIC AND VASOMOTOR SYMPTOMS AMONG MENOPAUSAL WOMEN RESIDING IN SELECTED VILLAGES AT DISTRICT BUDGAM, KASHMIR".*

BRIEF RESUME OF INTENDED WORK

INTRODUCTION

Fit at forty, strong at sixty, independent at eighty.

- (Indian Menopause Society, 2013)

Women experience various turning points in their life cycle, which may be developmental or transitional. Midlife is one such transitional period which brings about important changes in women. Menopause is a unique stage of female reproductive life cycle, a transition from reproductive to non reproductive stage. The word "menopause" literally means the "end of monthly cycles" from the Greek words pausis (cessation) and the word root men (month).1

Menopause is said to be a universal reproductive phenomenon, which can be perceived as unpleasant. This period is generally associated with unavoidable manifestation of aging process in women. Menopause may be smooth experience for some women with only symptom of cessation of menstrual flow while others face one or more of post menopausal symptom. In present era with increased life expectancy, women are likely to face long periods of menopause accounting to approximately a third of her life. 2

World Menopause Day is celebrated on 18th October every year. World Menopause Day started all the way back in 1984 and was instituted by the International Menopause Society and the World Health Organization (WHO).The Menopause day is devoted to creating awareness about one of the most difficult time in a women's life.3

In the developed world, mean life expectancy for women since 1990 has increased from 50 to 81 years. The life expectancy of the population around the world is estimated to be 75-80 years. Today, there are over 200 million postmenopausal women worldwide and 40 million in India. According to the world health organization they estimated that by 2025 there will be 1.1 billion women above the age of 50 years experiencing menopause and the average age of experiencing the symptoms of menopause is 47.5years.4

According to Indian menopause society research there are about 65 million Indian women over the age of 45 and estimated that in the year 2026, the population in India will be 1.4 billion, people over 60 years will be 173 million and the menopausal population will be 103 million. The average age of Indian menopausal women is 47.5 years. 5

A study was conducted to establish the age at onset of menopause and the prevalence of menopause and menopausal symptoms in South Indian women. 352 postmenopausal women attending the outpatient clinics of obstetrics and gynecology department of Dr TMA Pai Hospital, a tertiary care Hospital in South India, were included in the study. The Menopause-Specific Quality of Life (MENQOL) questionnaire was used for analysis and data were presented as percentages for qualitative variable. The study results revealed that the mean age at menopause was 48.7 years. Most frequent menopausal symptoms were aching in muscle and joints, feeling tired, poor memory, lower backache and difficulty in sleeping. The vasomotor and sexual domains were less frequently complained when compared to physical and psychological domains. The study concluded that the age at onset of menopause in southern Karnataka (India) is 48.7 years which is four years more than the mean menopause age for Indian women. 6

In this study 100 healthy post-menopausal women in and around Srinagar city were selected using simple random sampling technique to study the symptoms of menopause and the treatment options used by them.

The results reveal that the majority of post-menopausal women in Srinagar district of Kashmir valley had no knowledge of HRT or FSH and they did not make use of any coping strategy to avoid postmenopausal discomforts. They did not consult anyone to seek relief from post-menopausal discomforts. Further, post-menopausal women were not making use of any stress reduction techniques like yoga, acupuncture and meditation while as only few of them relied on prayers to reduce the stress related to menopause.7

Soya protein has a greater effect on bone in postmenopausal women not on hormone replacement therapy, as evidenced by reducing bone resorption and urinary calcium excretion. A total of 71 women were randomly assigned to either soya protein (SP) or milk-based protein (MBP), 40 g daily for 3 months, in a double-blind parallel design. Forty-two women completed the study (20 on SP and 22 on MBP. Overall, both protein supplements positively influenced serum IGF-T, known to correlate with bone formation. However, SP had a more pronounced effect on IGF-I than MBP. Urinary deoxypyridinoline (Dpd) excretion, a specific biomarker of bone resorption, was significantly reduced by SP, but not by MBP when all women were included. Furthermore, women on MBP experienced a 33% increase in urinary calcium excretion, whereas SP did not have such an effect. To evaluate whether SP affects women differently on the basis of their HRT status, data from women on HRT (n = 22) and those not on HRT (n = 20) were analyzed separately. The subanalysis of the data indicated that SP had the greatest impact on serum IGF –I (an increase of 97%) in the women not on HRT. The changes in urinary Dpd due to SP were only observed in women not on HRT, indicating that the overall decrease in Dpd occurred with SP in the absence of HRT. These results indicate that soya protein may 21 positively influence bone and calcium homeostasis in post menopausal women, particularly those not on HRT.8

Soya protein consumption and bone mass in early postmenopausal Chinese women. The sample comprised 454 healthy Chinese women (mean age 55.1 +/- 3.57) within the first 12 years of postmenopause. We estimated the dietary intake of soya protein and isoflavones, and other key nutrients, including dietary protein and calcium, using the quantitative food frequency method. Noted a dose-response relationship with increasing higher BMD values at the trochanter, intertrochanter as well as the total hip and total body with increasing soya protein intake quartiles (P<0.05 from tests for trend). The BMD values differed by about 4-8% between the first and fourth soya protein intake quartiles. Though women from the fourth intake quartile had a 2.9% higher BMD value compared with those from the first intake quartile, the difference was not statistically significant. The effects of soya protein and soya isoflavones on, bone health should be further explored in populations with habitual dietary soya intake.9

The effect of a soya rich diet on the vaginal epithelium in postmenopausal analyzed double blind trial. In this study, we analyzed the effects of a 6-month soya-rich diet on the vaginal epithelium of asymptomatic postmenopausal women in a randomized clinical trial. 187 women were recruited for the study and divided into three groups: a phytoestrogen rich diet group; a hormonal replacement group, and a control group. A vaginal sample for hormonal cytology was taken before and at the end of the study, and sent unnamed to a cytologist.10

A study on acupuncture treatment for menopausal hot flashes. To investigate the feasibility of conducting a randomized trial of the effect of acupuncture in decreasing hot flashes in peri- and postmenopausal women between 45-56 years. Fifty-six women ages 44 to 55 with no menses in the past 3 months and at least four hot flashes per day were recruited from two clinical centers and randomized to one of three treatment groups: usual care (n = 19), sham acupuncture (n = 18), or Traditional Chinese Medicine acupuncture (n = 19). Acupuncture treatments were scheduled twice weekly for 8 consecutive weeks. The sham acupuncture group received shallow needling in non therapeutic sites. The Traditional Chinese Medicine acupuncture group received one of four treatments based on a Traditional Chinese Medicine diagnosis. Usual care participants were instructed to not initiate any new treatments for hot flashes during the study. Daily diaries were used to track frequency and severity of hot flashes. The mean daily index score was based on the

number of mild, moderate, and severe hot flashes. Follow-up analyses were adjusted for baseline values, clinical center, age, and body mass index. There was a significant decrease in mean frequency of hot flashes between weeks 1 and 8 across all groups (P = 0.01), although the differences between the three study groups were not significant. However, the two acupuncture groups showed a significantly greater decrease than the usual care group (P < 0.05), but did not differ from each other. Results followed a similar pattern for the hot flash index score. There were no 23 significant effects for changes in hot flash interference, sleep, mood, health-related quality of life, or psychological well-being. These results suggest either that there is a strong placebo effect or that both traditional and sham acupuncture significantly reduce hot flash frequently.11

A study on Treating the climacteric symptoms in Indian women with an integrated approach to yoga therapy: a randomized control study. To study the effect of yoga on the climacteric symptoms, perceived stress, and personality in perimenopausal women between 45-56 years. One hundred twenty participants (ages 40-55 years) were randomly divided into two study arms, ie, yoga and control. The yoga group practiced an integrated approach to yoga therapy comprising surya namaskara (sun salutation) with 12 postures, pranayama (breathing practices), and avartan dhyan (cyclic meditation), whereas the control group practiced a set of simple physical exercises under supervision of trained teachers for 8 weeks (1 h daily, 5 days per week). The assessments were made by Greene Climacteric Scale, Perceived Stress Scale, and Eysenck's Personality Inventory before and after the intervention. Of the three factors of the Greene Climacteric Scale, the Mann-Whitney test showed a significant difference between groups (P < 0.05) in the vasomotor symptoms, a marginally significant difference (P = 0.06) in psychological factors but not in the somatic component. Effect sizes were higher in the yoga group for all factors. There was a significantly greater degree of decrease in Perceived Stress Scale scores (P < 0.001, independent samples t test) in the yoga group compared with controls (between-group analysis) with a higher effect size in the yoga group (1.10) than the control (0.27). On the Eysenck's Personality Inventory, the decrease in neuroticism was greater (P < 0.05) in the yoga group (effect size = 0.43) than the control group (effect size = 0.21) with no change in extroversion in either the yoga or control group. Eight weeks of an integrated approach to yoga therapy decreases climacteric symptoms, perceived stress, and neuroticism in premenopausal women between 45-56 years better than physical exercise.12

NEED FOR THE STUDY

Although menopause is natural process, almost all women during and after the menopause suffer from typical symptoms with approximately 40%seeking a medical help for various symptoms like vasomotor, psychological, urogenital, musculoskeletal symptoms. Recent studies failed to show the protective effect of hormone replacement therapy in reducing the risk of coronary artery disease and have revealed an increased risk of heart disease, stroke and invasive breast cancer13. So there is need of natural approaches to relieve menopausal discomfort and soya is considered as "super food "for relieving menopausal symptoms.

Soybean is commonly called wonder bean since it is an excellent source of nutrients such as proteins, fats, carbohydrates, vitamins and minerals. . It contains 43 gm of protein per 100 gm which is the highest among the pulses. It also contains 19.5 gm of fat, 21 gm of carbohydrate and provides 432 kcal per 100 gm. Soybean also contains a family of chemical compounds called phytoestrogens. Phytoestrogens have chemical structures similar to the estrogens produced in the body and it is believed that eating foods rich in phytoestrogens can help alleviate low estrogen production in the body. Isoflavones are the active ingredients in soybeans which have estrogen-like properties .Isoflavones reduces menopausal symptoms, blood cholesterol level, incidence of cancer and osteoporosis. Eating 100gm of soya protein per day provides

200 mg of soya isoflavones .A target range of 80-160 mg of isoflavones per day is needed for adequate relief of menopausal symptoms .Soybean is used extensively as human food, animal feed and for industrial purposes. All the products of soybean are of dietary importance such as soybean cheese, soybean milk, soybean oil, soybean meal.14

A study was conducted to review randomized, controlled trials of complimentary therapies for menopausal symptoms in order to better inform practice and guide future research. 29 randomized, controlled clinical trials of complimentary therapies for hot flushes and other menopausal symptoms were identified; and of these 12 dealt with soy or soy extracts, 10 with herbs, and 7 with other complimentary therapies. This study concluded that food containing phytoestrogens show promise for the treatment of menopausal symptoms. The best source is soya in various forms such as soya beans, fortified soya milk, tofu and soya flour which contain high levels of isoflavones and calcium.15

A double blind randomized study was conducted in tertiary care centres united states to assess the effect of soy protein containing isoflavones on quality of life in post menopausal women. A sample of 93 healthy, ambulatory women were randomly assigned to receive 20 gm of soya protein containing 160 mg of isoflavones versus matched placebo (20gm whole protein milk) and quality of life was assessed by menopause-specific quality of life questionnaire . The study results revealed that there was a significant improvement in all 4 quality of life scales (vasomotor, psychosexual, physical and sexual) among the women taking soy protein and no changes were seen in placebo, the study concluded that use of soya isoflavones as an alternative to oestrogen therapy may be potentially safeful and seeming safe in women who are looking for relief from menopausal symptoms.16

A study was conducted in selected villages of Coimbatore district, Tamil Nadu to assess the effectiveness of soya bean consumption on menopausal symptoms among women between 45-56 years. A sample of 60 menopausal women from 2 villages were selected by convenient sampling technique and divided 30 into experimental and 30 into control group.60gm of cooked soya bean was administered to experimental group 2 times daily and no intervention was been given to control group. Self administered questionnaire was used to measure the menopausal symptoms before and after soya bean consumption. The study results revealed that post test mean 11.5 was lesser than pretest mean 14.5 in experimental group. The obtained' value 7.761 was highly significant at 0.05 level. The study concluded that soya bean consumption was effective on menopausal symptoms.17

A study on Sex and long-term soya diets affect the metabolism and excretion of soya isoflavones in humans Soya bean consumption may be protective against hormone-dependent cancers, possibly in part because of the isoflavones daidzein and genistein, which are weakly estrogenic. This paper reviews our studies of the metabolism and disposition of these phytoestrogens in humans. During 1 mo of daily soya ingestion in a metabolic unit [1.065 L (36 oz) soya milk, providing 80-210 mg of each isoflavones daily], women initially excreted more 29 isoflavone conjugates in urine than did men. Recoveries of conjugates of genistein, daidzein, and equol were 24%, 66%, and 28% of the amounts ingested in women, respectively, and 15%, 47%, and 15%, respectively, of those in men. A progressive decrease in urinary excretion of genistein and daidzein was observed in women but not in men during the study. At least 10% of ingested daidzin was excreted in urine as equol conjugate in one man and one woman after the first soya ingestion. Three more women but no more men developed the ability to produce and excrete large amounts of equol. Absorption rate constants (k(e)) of the isoflavones were estimated to be 0.24-0.50 h(-1). The elimination rates (k(e)) for genistein, daidzein, and equol were 0.1, 0.16, and 0.08 h(-1), respectively, in women and 0.19, 0.25, and 0.13 h(-1), respectively, in men. Thus, the excretion half-life values of genistein were longer in women (7, 4, and 9 h, respectively) than in men (4, 3, and 5 h, respectively) after the first soya ingestion. The excretion half-life shortened progressively in women but lengthened progressively inmen over the study period.18

A study on Legume Consumption and Risk of Coronary Heart Disease in Men and Women may be associated with a reduced risk of coronary heart disease (CHD). Soya bean protein and dietary fiber supplementation reduce serum cholesterol in randomized controlled trials. Consumption of legumes, which are high in bean protein and water-soluble fiber. A total of 9632 men and women who participated in the First National Health and Nutrition Examination Survey Epidemiologic Follow-up Study (NHEFS) and were free of cardiovascular disease (CVD) at their baseline examination were included in this prospective cohort study. Frequency of legume intake was estimated using a 3-month food frequency questionnaire, and incidence of CHD and CVD was obtained from medical records and death certificates Legume consumption was significantly and inversely associated with risk of CHD (P = .002 for trend) and CVD (P = .02 for trend) after adjustment for established CVD risk factors. Legume consumption 4 times or more per week compared with less than once a week was associated with a 22% lower risk of CHD (relative risk, 0.78; 95% confidence 30 interval, 0.68-0.90) and an 11% lower risk of CVD (relative risk, 0.89; 95% confidence interval, 0.80-0.98).19

A study on Protective effects of dietary phytoestrogens in chronic renal disease Phyto estrogens are naturally occurring plant compounds that are present primarily in soya beans as isoflavones and in flaxseed as lignans. Because of their structural similarity to endogenous estrogens, phytoestrogens bind to both estrogen receptors (ER)-alpha and beta (but more strongly to ER-beta) and exert estrogen-like effects. There is increasing evidence that dietary phytoestrogens have a beneficial role in chronic renal disease. Nutritional intervention studies have

shown that consumption of soya-based protein and flaxseed reduces proteinuria and attenuates renal functional or structural damage in animals and humans with various forms of chronic renal disease. It is not clear which component(s) of the soya bean or 31 flaxseed is (are) responsible for the protective effects observed in experimental animals and in limited studies in humans. Vegetable protein has been shown to have a beneficial effect on renal disease in animals and humans. Thus, the role of soya and flaxseed cannot be ruled out. Isoflavones and lignans are readily absorbed from the gut and converted to active metabolites, which may be partly responsible for the beneficial renal effects of soya protein and flaxseed. In addition, an interaction between type of protein and phytoestrogens is also possible. The biological actions of isoflavones and lignans have been well defined in different cell types in vitro and also in vivo, but how these compounds might reduce renal injury remains to be elucidated. Possible mechanisms include inhibition of cell growth and proliferation via ER-mediated mechanisms or non-ER-mediated pathways through inhibition of tyrosine protein kinases, modulation of growth factors involved in extracellular matrix synthesis and fibrogenesis, inhibition of cytokine-induced activation of transcription factors, inhibition of angiogenesis, antioxidative action, and suppression of platelet activating factor and platelet aggregation, and immunomodulatory activity. To date, clinical trials in humans are few, of relatively short duration, and involve a small number of patients. Prospective randomized trials are needed to evaluate the long-term safety and effectiveness of dietary phytoestrogens on renal disease progression in patients with chronic renal failure.20

A study on isoflavone Cardiovascular and renal benefits of dry bean and soya bean intake. Dry beans and soya beans are nutrient dense fiber- rich, and are high-quality sources of protein. Protective and therapeutic effects of both dry bean and soya bean intake have been documented. Studies show that dry bean intake has the potential todecrease serum cholesterol concentrations, improve many aspects of the diabetic state, and provide metabolic benefits that aid

In weight control. Soya beans are a unique source of the isoflavones genistein and diadzein, which have numerous biological functions. Soya beans and soya foods potentially have multifaceted health-promoting effects, including cholesterol reduction, improved vascular health, preserved bone mineral density, and reduction of menopausal 32 symptoms. Soya appears to have salutary effects on renal function, although these effects are not well understood. Whereas populations consuming high intakes of soya have lower

prevalence of certain cancers, definitive experimental data are insufficient to clarify a protective role of soya. The availability of legume products and resources is

increasing, incorporating dry beans and soya foods into the diet can be practical and enjoyable. With the shift toward a more plant-based diet, dry beans and soya will be potent tools in the treatment and prevention of chronic disease.21

A study on soya isoflavones intake and estrogen excretion patterns in young women effect of probiotic administration. It was measured in 36 healthy premenstrual women before and after the injection of soya protein formula containing 120mg of isoflavones daily for one month, result was soya isoflavones injections include qualitative differences in urinary excretion of estrogen metabolites and isoflavones but failed to alter 20 HE1/16 alpha OHEI ratios. They find out that isoflavones rich soya protein administration alone or with probiotic supplement, did not alter urinary excretion of estrogen metabolites in premenopausal women between 45-56 years. However adding concentrated probiotics may alter isoflavones bio availability.22

study on efficiency and safety of a soya isoflavones extract in post menopausal women between 45-56 years. In this double blind randomized placebo – controlled study a total of 80 women (Mean age = 55.1 years) who reported 5 or more hot flushed episodes per day were randomized to receive either 250 mg of standardized soya extract a total of 100 mg/ day of isoflavones (n=40) or placebo (m=40). The mean number of hot flushness was 9.6 + 1-3.9 per day in the isoflavones group and 10.1 + 1-4.9 in the placebo group (p70.05) after 10 months there was a significant reduction in both group. The soya isoflavones extract exerted favorable effect as vasomotor symptoms and good compliance providing a safe and effective alternative therapeutic for post menopausal women between 45-56 years.23

A study on effect of soya germ extracts on blood lipo proteins, anti oxidative capacity and urinary estrogen metabolites in post menopausal women between 45-56 years as hormones therapy. A1 subject received 6g of soya germ extract per day for 4 weeks. It is inferred that plasma HDL/C level increased markedly with significant decrease of plasma LDL-C/ HDL-C ratio and LDL14 T4 levels. That concluded soya germ extract may improve serum lipid profile in post menopausal Taiwanese women who receive HT, and probably provide a favorable

effect on estrogen metabolism.24

A study on association between soya nut consumption and decrease menopausal symptoms. Sixty health post menopausal women between 45-56 years were randomized in a cross over design to a therapeutic life style changes. TLC diet alone and TIC diet of similar energy, fat and protein content in which one half cup of soya nuts divided into three or four portions spaced throughout a day containing (259 of soya protein during each 8 week diet period). Subjects recorded the number of hot flushes and amount of exercise daily. It is inferred that compared to the TLC diet alone the TLC diet plus soya nuts was associated with a 45% decrease in hot flushes (7.5+1 – 3.6 VS. 4.1+/-2.6 hot flushes day respectively, p<0.001) in women with >4.5 hot flushes/day at baseline and 41% in those = 4.5 hot flushes/day (2.2+1-1.2 vs 1.3+1-1.1, respectively, p<0.001) soya nut intake was also associated with significant improvement in score on the menopausal symptoms quality of life questionnaire 19% decrease in vasomotor score (p=0.004) 12.9% reduction in psychosocial score (p=0.01) 7.9% decrease in physical score (p=0.045) and trends towards improvement in the sexual score with a 17.7% reduction in symptoms (p=0.129). Substituting soya nuts for non soya protein in a TIC diet and consumed three or four times throughout the day is associated with a decrease in hot flushness and improve in menopausal symptoms.25

Soya also helps to promote better health and has gain health benefits in preventing metabolic disorders, cancer and cardiovascular conditions. This motivated the investigator to assess the effect of soya bean on menopausal symptoms.

6.2 REVIEW OF THE LITERATURE

The literature relevant to this study was reviewed and organized in the following headings.

Literature related to Menopausal symptoms

Literature related to soya bean consumption

Literature related to Effect of soya bean consumption on menopausal symptoms

Literature related to menopausal symptoms

A population based survey was carried out on a representative sample of 495 Singaporean migrant women aged 40 to 60 to determine the prevalence of 17 menopausal symptoms. The mean age of participants was 49 years and the classical menopausal symptoms found were hot flushes (17.6%), vaginal dryness (20.7%) and night sweats (8.9%). The most prevalent symptom reported was low backache with aching muscle joints (51.4%). The most well-known effect of these is the "hot flash" or "hot flush", a sudden temporary increase in body temperature. These symptoms were reported due to hormonal changes underlying menopause, which are caused by aging, other health states, psychosocial factors and life style.26

A cross sectional study on 500 postmenopausal women from rural areas attending OBG clinic at Government medical college, Jammu India. This study showed that the mean age of menopause was 49.35 years and the predominant symptoms were fatigue and lack of energy 70% ,rheumatology related symptoms -60%, Cold sweats, Weight gain , Irritability and nervousness 50%.Dyslipidemia was seen in 39% and metabolic syndrome in 13%. In this study group 10% had a hectic lifestyle, 55% sedentary and 35% had moderate lifestyle. Only 5% of women received Hormonal Replacement therapy. Among these women 2.4% were hypertensive, 9% diabetic and 8% of them had dyslipidemia. The study concluded that there is an alarmingly high prevalence of cardiovascular risk factors especially diabetes, hypertension, dyslipidaemia and obesity in postmenopausal women from rural areas.27

A cross-sectional study was conducted on perceptions regarding menopause, prevalence of menopausal symptoms and association of family environmental factors with menopausal symptoms among 100 postmenopausal and 100 perimenopausal rural women in south India.57% of postmenopausal women perceived menopause as convenient. The study findings revealed that 69% of them complained of diminishing abilities after menopause.23% felt that sexual life ends with the onset of menopause, 16% reported that their husbands had become disinterested in them after menopause and 11% were apprehensive about the loss of femininity. A higher proportion of menopausal women reported hot flushes, night sweats, urge incontinence and other somatic symptoms. The study concluded that there was significant associations between multiple somatic symptoms, vasomotor symptoms, urge incontinence, loss of sexual desire, and menopause.28

A cross-sectional study was conducted on factors associated with menopausal symptoms and their relationship with the quality of life. Data was collected from 886 women of mean age 48.62 years with a questionnaire including demographic variables, quality of life and menopause symptom checklist. The study revealed statistically significant variables like health problems, recent life stresses, absence of relaxation methods, number of pregnancies, inadequate and unbalanced nutrition, age and dissatisfaction in marriage. There was negative relation between menopausal symptom scores and quality of life scores. Study recommended that stress management and health-promoting practices should be incorporated into menopausal care programmes to improve health and quality of life of middle aged women.29

A study was conducted to evaluate the cross-sectional relationships of diet and other lifestyle variables to menopause. A total of 4186 female residents aged 45-55 in Takayama City, Japan, responded to a self-

administered questionnaire (the response rate was 89.3%). Diet in the past year was assessed by semi quantitative food frequency questionnaire. Using the logistic regression model, associations between study variables and menopausal status were estimated in terms of odds ratio (OR). The study result shows that Nulliparity and lower relative weight were significantly associated with menopause after controlling for age ($P < 0.05$). The association of smoking with menopause was marginally significant after controlling for age ($P = 0.06$). Higher intakes of fat, cholesterol, and coffee were inversely and significantly associated with later menopause after controlling for age, total energy, parity, menarche age, and relative weight (ORs for the highest tertiles of fat, cholesterol and coffee intakes were 0.78, 0.79, and 0.70, respectively, $P < 0.05$). The highest tertiles of calcium and soy product intakes were significantly associated with menopause after controlling for the covariates (ORs = 1.25 and 1.42, respectively, $P < 0.05$).The study concluded that dietary factors appear to be associated with onset of menopauses.30

A study was conducted to find out the variation in menopausal symptoms with age, education and working/non working status in North-Indian sub population. The MRS scale, a self administered standardized questionnaire was applied with additional patients related information for analysis. The results were evaluated for psychological, somatic and urogenital symptoms average age at which menopause set in the cohort was found to be 48.7$\pm$2.3yrs.The cohort was divided into peri (35-45) menopausal, early, menopause (46-51) and the postmenopausal (52-65). A significantly higher % of perimenopause women (36%) showed a psychological score ≥ 7 while a higher % of postmenopausal women showed somatic score and urogenital score ≥ 7 .Working women suffer more from psychological symptoms whereas non-working women showed a greater incidence of somatic symptoms. Educated women showed a lower incidence of psychological and somatic symptoms. Thus, the study concludes that age; level of education and working/non working status may also contribute to significant variation of menopausal symptoms.31

Literature related to soya bean consumption

A case cohort study was conducted to assess the association of soy food intake after diagnosis of breast cancer with mortality and cancer recurrence among 5042 female breast cancer survivors in china. women aged 20 to 75years with diagnoses between march 2002 and April 2006 were recruited and followed up through june2009 .Information on cancer diagnosis and treatment , life style exposures after cancer diagnosis and disease progression was collected at approximately 6 months after cancer diagnosis and was reassessed at 3 follow-up interviews conducted at 18, 36, and 60 months after diagnosis. Annual record linkage with the Shanghai Vital Statistics Registry database was carried out to obtain survival information for participants who were lost to follow-up. Medical charts were reviewed to verify disease and treatment and Total mortality and breast cancer recurrence or breast cancer–related deaths. Cox regression analysis was carried out with adjustment for known clinical predictors and other lifestyle factors. Soy food intake was treated as a time-dependent variable. The study results revealed that During the median follow-up of 3.9 years (range, 0.5-6.2 years), 444 deaths and 534 recurrences or breast cancer–related deaths were documented in 5033 surgically treated breast cancer patients. Soy food intake, as measured by either soy protein or soy isoflavone intake was inversely associated with mortality and recurrence. The hazard ratio associated with the highest quartile of soy protein intake was 0.71 (95% confidence interval [CI], 0.54-0.92) for total mortality and 0.68 (95% CI, 0.54-0.87) for recurrence compared with the lowest quartile of intake. The multivariate-adjusted 4-year mortality rates were 10.3% and 7.4%, and the 4-year recurrence rates were 11.2% and 8.0%, respectively, for women in the lowest and highest quartiles of soy protein intake. The inverse association was evident among women with either estrogen receptor–positive or –negative breast cancer and was present in both users and nonusers of tamoxifen. The study concluded that, soy food consumption was significantly associated with decreased risk of death and recurrence among women with breast cancer.32

A Randomized, double-blind, controlled trial was conducted on Three communities in the People's Republic of China to examine the effect of soybean protein supplementation on blood pressure in persons with pre hypertension or stage1 hypertension. 302 participants 35 to 64 years of age with an initial untreated systolic blood pressure of 130 to 159 mm Hg, diastolic blood pressure of 80 to 99 mm Hg, or both were randomly assigned to receive 40 gm of isolated soybean protein supplements per day or complex carbohydrate control for 12 weeks. Blood pressure measurements were obtained by using random-zero sphygmomanometers at baseline at 6 and12 weeks. The study result revealed at baseline, the mean systolic and diastolic blood pressures were 135.0 mm Hg (SD 10.9) and 84.7 mm Hg (SD 6.9), respectively. Compared with the control group, the net changes in systolic blood pressure and diastolic blood pressure were -4.31mm Hg (95% CI, -2.11 to -6.51 mm Hg; P < 0.001) and -2.76mm Hg (CI, -1.35 to -4.16 mm Hg; P < 0.001), respectively, after the 12-week intervention. The net changes in systolic and diastolic blood pressure reductions were -7.88 mm Hg (CI, -4.66to -11.1 mm Hg) and -5.27 mm Hg (CI, -3.05 to -7.49 mmHg), respectively, in persons with hypertension and -2.34 mm Hg(CI, 0.48 to -5.17 mm Hg) and -1.28 mm Hg (CI, 0.52 to -3.07mm Hg), respectively, in those without hypertension. The study concluded that Soybean protein supplementation resulted in a reduction in systolic and diastolic blood pressure and increased intake of soybean protein may play an important role in preventing and treating hypertension.33

A study was conducted by department of medicine, university of hull, U.K to assess the effect of dietary supplement with soy protein and isoflavones on insulin resistance, glycemic control, and cardiovascular risk markers in women aged 56-69 with type 2 diabetes .A total of 32 women with diet-controlled type 2 diabetes completed a randomized, double blind, cross-over trial of dietary supplementation with phytoestrogens (soy protein 30 g/day, isoflavones 132 mg/day) versus placebo (cellulose 30 g/day) for 12 weeks, separated by a 2-week washout period. The study results revealed that Compliance with the dietary supplementation was >90% for both treatment phases. When compared with the mean percentage change from baseline seen after 12 weeks of placebo, phytoestrogen supplementation demonstrated significantly lower mean values for fasting insulin (mean ± SD 8.09 ± 21.9%, P = 0.006), insulin resistance (6.47 ± 27.7%, P = 0.003), HbA1c(0.64 ± 3.19%, P = 0.048), total cholesterol (4.07 ± 8.13%, P = 0.004), LDL cholesterol (7.09 ± 12.7%, P = 0.001), cholesterol/HDL cholesterol ratio (3.89 ± 11.7%, P = 0.015), and free thyroxine (2.50 ± 8.47%, P = 0.004).The study concluded that dietary supplementation with soy phytoestrogens favourably alters insulin resistance, glycemic control, and serum lipoproteins in postmenopausal women with type 2 diabetes, thereby improving their cardiovascular risk profile.34

A population-based prospective cohort study of 75,000 Chinese women aged 40– 70 yrs at the baseline survey was conducted from 1997 to 2000 in japan to examine the relationship between soy food intake and incidence of coronary heart disease (CHD). Participants included in this study were 64,915 women without previously diagnosed CHD, stroke, cancer and diabetes at baseline. Information on usual intake of soy foods was obtained at baseline through an in-person interview using a validated food-frequency questionnaire. Cohort members were followed biannually through in-person interviews. After a mean of 2.5 yrs (162,277 person-years) of follow-up, 62 incident cases of CHD (43 nonfatal myocardial infarctions and 19 CHD deaths) were documented. There was a clear monotonic dose-response relationship between soy food intake and risk of total CHD (P for trend = 0.003) with an adjusted relative risk (RR) of 0.25 (95% CI, 0.10–0.63) observed for women in the highest vs. the lowest quartile of total soy protein intake. The inverse association was more pronounced for nonfatal myocardial infarction (RR = 0.14; 95% CI, 0.04–0.48 for the highest vs. the lowest quartile of intake; P for trend = 0.001). This study provides, for the first time, direct evidence that soy food consumption may reduce the risk of CHD in women.35

A randomized cross-over clinical trial was conducted to determine the effects of soy consumption on markers of inflammation and endothelial function in postmenopausal women with the metabolic syndrome. This study included 42 postmenopausal women with the metabolic syndrome. Participants were randomly assigned to consume a control diet (Dietary Approaches to Stop Hypertension [DASH]), soy protein diet, or

soy nut diet, each for 8 weeks. Red meat in the DASH diet (one serving/day) was replaced by soy protein in the soy protein diet and by soy nut in the soy nut diet. The results for nitric oxide levels, the difference from the control diet was 9.8% ($P < 0.01$) on the soy nut and −1.7% ($P = 0.10$) on the soy protein diets. The difference from the control diet for serum E-selectin was −11.4% ($P < 0.01$) on the soy nut consumption and −4.7% ($P = 0.19$) on the soy protein diet. Soy nut consumption reduced interleukin-18 compared with the control diet (difference from the control diet: −9.2%, $P < 0.01$), but soy protein did not (difference from the control diet: −4.6%, $P = 0.14$). For C-reactive protein, the difference from the control diet was −8.9% ($P < 0.01$) on the soy nut diet and −1.6% ($P < 0.01$) on the soy protein diet. The results revealed that Short-term soy nut consumption reduced some markers of inflammation and increased plasma nitric oxide levels in postmenopausal women with the metabolic syndrome. 36

Literature related to Effect of soya bean consumption on menopausal symptoms

A study was conducted to examine the safety and efficacy of an oral soy isoflavone extract on 177 postmenopausal women (mean age 55 years) experiencing five or more hot flashes per day. In this double-blind, placebo-controlled study the women were randomized to receive either soy isoflavone extract or placebo. Analysis after 12weeks showed a statistically significant reduction in average hot flash severity and frequency in the soy isoflavone group compared with the placebo group. In addition, decreases in the incidence and severity of hot flashes occurred as soon as 2 weeks in the soy group; whereas, the placebo group experienced no relief the first four weeks. 37

A double-blind prospective study was done on soya Isoflavone treatment for acute menopausal symptoms among sixty healthy postmenopausal women who were randomly assigned by computer into two groups to receive 60 mg soya isoflavones or placebo daily for 3 months. Climacteric symptoms were recorded before and after treatment, the study results revealed that hot flushes and night sweats were reduced by 57% and 43%, respectively. The study concluded that soya isoflavones could be used to relieve acute menopausal symptoms.38

A study was conducted to evaluate The effect of soy-derived isoflavones over hot flushes, menopausal symptoms and mood in climacteric women with increased body mass index .Fifty symptomatic climacteric women aged 40 to 59 with increased BMI (≥ 25) were recruited to receive oral 100 mg/day of soy derived isoflavones for 3 months. Hot flushes (frequency/intensity), menopausal symptoms (Menopause Rating Scale [MRS]) and mood (Hamilton Depressive Rating Scale [HDRS]) were evaluated at baseline and at 90 days. Study results After 3 months of soy isoflavone supplementation revealed that hot flushes significantly decreased in percentage, number and severity (100% to 31.1%; 3.9 ± 2.3 to 0.4 ± 0.8 and 2.6 ± 0.9 to 0.4 ± 0.8, respectively, $p < 0.001$). MRS scores (total and for subscales) reflecting general menopausal symptoms also significantly decreased compared to baseline. Regarding mood, after three months total HDRS scores and the rate of women presenting depressed mood (scores ≥ 8) significantly decreased (16.3 ± 5.4 to 6.9 ± 5.2 and 93.3% to 28.9%, respectively, $p < 0.05$).the study concluded that In high risk climacteric population, soy derived isoflavone treatment improves mood as well as vasomotor and general menopausal symptoms.39

A randomized, double-blind, placebo-controlled trial study was done among 104 post menopausal women to assess the effect of dietary soy supplementation on hot flashes in postmenopausal women. 51 patients took 40 gm of isolated soya protein daily and 53 patients took 60 gm placebo (casein) daily. The study lasted for 12 weeks and using analysis of covariance baseline in mean number of moderate to severe hot flushes including night sweats during treatment was analyzed .The study results revealed that in women taking soy had a 26%reduction in mean number of hot flushes by week 3 and 33%reduction by week 4 and

45%reducction by week 12 versus 30%reduction obtained with placebo group. Study concluded that soy protein diet reduces hot flushes in menopausal women.40

A prospective randomized double blind study was conducted to evaluate the effects of herbo mineral phyto oestrogen formulation containing soya iso-flavones in Indian women with signs and symptoms of menopause among 60 peri and post menopausal women in a public hospital. Women with symptoms related to menopause were randomized to either group A or group B(placebo) menopausal symptoms were graded along a scale of kupper man index at base line and changes were noted every 2 months and there after for a total of 6 months. The group that received herbo mineral phyto oestrogen showed 40% of improvement in psychological symptoms compared to placebo group .Improvement was noted in vasomotor symptoms,symptoms relating to sexual activity and urinary symptoms in group A.Study concluded that herbo mineral phyto oestrogen containing soya isoflavones is effective in management of symptoms in menopausal women.41

A double blind, placebo controlled trial study was conducted to examine effects of 6 months supplementation of isoflavone rich soy protein on menopausal symptoms ,lipid profiles and bone density in postmenopausal women. In this study 100 healthy postmenopausal women not taking Hormone Replacement Therapy, were randomly assigned to consume either 25gm soy protein containing 75 mg isoflavones (study group) or 25 gm casein protein(control group) daily. Monthly assessment for acceptability & side effects, 3 monthly for menopausal symptoms (Kupperman Menopausal Index; KMI) and serum lipid-profile, 6 monthly for Follicular stimulating hormone, Estradiol levels, vaginal cytology, endometrial thickness and bone density were done. T-test, analysis of variance (ANOVA) and chi square tests were employed. In Result higher number of cases reported improvement in hot-flashes, joint-pains and vaginal-dryness on soy treatment ($p<.05$). Soy supplement was significantly superior to placebo in reducing KMI ($p<.05$). Soy group showed 7.7% decrease in total cholesterol and 14% decrease in LDL study concluded that 25gm soy supplement containing 75mg of isoflavones may be an effective alternative therapy for menopausal symptoms and may offer a benefit to cardiovascular-system by altering lipid-profile favorably. Supplementation of Soy protein isolate containing phyto estrogens in significantly decreases total and low density cholesterol and improves menopausal symptoms as compared to placebo.42

A longitudinal study was conducted among 34 women to investigate effect of soybean and isoflavone intake on bone mineral density (BMD) and its change among young Korean women over 2 years, The BMD was measured 3 times with 1-year intervals by dual x-ray absorptiometry at the lumbar spine and femur (neck, Ward's triangle [WT], and trochanter). Dietary intake was assessed up to 8 times by 24-hour recall with average 4-month interval. During,this study period that ,BMD increased significantly for lumber spine and WT (2.5% and 5.2%). The average daily intake of soy beans and isoflavones was 39 gm and 8 mg, respectively. soybean intake and total isoflavone intake had positive correlation on femoral neck (FN) and WT. By longitudinal mixed-model regression analysis, BMD increased 0.26% per 1 mg of isoflavone intake per year in the FN and 0.31% for WT ($P = .05$ and $.008$). The study concluded that soybean and isoflavone intake have a positive effect on the change of BMD on the FN and WT among young Korean women.43

statement of the problem

"A study to assess the effectiveness of soya beans on somatic and vasomotor symptoms among menopausal women residing in selected villages" at district Budgam, Kashmir"

6.3 OBJECTIVES OF THE STUDY

1. To assess the somatic and vasomotor symptoms among menopausal woman before the consumption of soya bean in experimental group.

2. To evaluate the effectiveness of soya bean consumption on somatic and vasomotor symptoms in experimental group.

3. To find out the association between pre-test and post-test scores of somatic and vasomotor symptoms among menopausal women in the experimental and control group.

4. To find out the association between pre-test and post-test scores of somatic and vasomotor symptoms with the selected demographic variables.

5. To determine the relationship between post-test level of somatic and vasomotor symptoms among menopausal women in the experimental group and control group.

6.4. OPERATIONAL DEFINITIONS

Effectiveness

In this study it refers to outcome of soya bean consumption on somatic and vasomotor symptoms among menopausal women between 45-56 yrs as measured by pre-test and post-test menopausal symptoms.

Soya bean

Soya bean belonged to legume family, rich in calcium, high in fibre and protein, low in saturated fat, cholesterol free, lactose free, a good source of omega 3 fatty acid high in phyto estrogens that mimic the action of the hormone estrogen. In this study it refers to consumption of cooked soya bean 60grams daily for 6 Weeks.

Menopausal symptoms

It refers to Wiklund menopausal symptom scale, rating the severity of 10 menopausal symptoms; hot flashes, sleep disturbances, Night sweat, fatigue, vaginal dryness, headache, irritability, joint pain, Feeling tense., palpitations .

Somatic Symptoms In this study it includes sleep disturbances, fatigue, Headache, Muscle and joint pain, irritability ,vaginal dryness and Feeling tense.

Vasomotor Symptoms

Vasomotor Symptoms are those symptoms that occur due to the construction or dilation of blood vessels. They include hot flashes, night sweats and heart palpitations.

Menopausal Woman It refers to woman after the cessation of menstruation.

Villages

It refers to the person with menopausal symptoms living in same settings with same culture, custom, norms and having same geographical boundries, road connectivity, health facility, power facility and water facility. Here village refers to Badram,Makhama ,Aadina etc.

6.5 ASSUMPTIONS

Women between 45 – 56 years may suffer from menopausal symptoms.

Women those who are taking soya bean may experience less menopausal symptoms.

Reduction of menopausal symptoms may improve the quality of life of menopausal women.

6.6. HYPOTHESIS

HO:-There is no significant difference between the somatic and vasomotor symptoms before and after soya bean consumption among women between 45-56 yrs in control and experimental group.

H1. There is a significant difference between pre and post test scores of somatic and vasomotor symptoms among menopausal women before and after soya been consumption in the experimental group.

H2. There is a significant difference between the post interventional level of somatic and vasomotor symptoms of menopausal women between the experimental and control group.

H3.There is a significant association between the pre-test and post-test scores of somatic and vasomotor symptoms among menopausal women and selected demographic variables in the experimental, control group.

H4. There is significant relationship between post-test level of somatic and vasomotor symptoms among menopausal women in the experimental group and control group.

7. MATERIALS AND METHODS

7.1 SOURCE OF DATA

Data will be collected from menopausal women between 45-56 years of age in selected villages of district Budgam.

7.1.1. RESEARCH APPROACH

Evaluative research approach

RESEARCH DESIGN

Quasi experimental research design

7.1.3 VARIABLES UNDER THIS STUDY

Independent variable - Soya bean consumption

Dependent variable - Somatic and vasomotor symptoms.

Socio-demographic variables - Age, Education, Income, Type of family, Number of children, Medical problems, Treatment taken, Menopause attained, Age at menarche , Religion, occupation.

7.1.4 SETTINGS OF THE STUDY

The research will be conducted in selected villages at district Budgam Kashmir. The location for conducting a study is termed as setting of the study. The study will be conducted in selected villages of tehsil Magam which includes :- Badran(6000) ,Adina(1,217) ,Makhama(4644).

7.1.5 POPULATION

Target Population

Population for the study comprises of menopausal women between 45-56yrs.

Accessible Population

Population for the study comprises of menopausal women between 45-56yrs in selected villages of district Budgam Kashmir.

SAMPLE

The Menopausal women who fulfil the inclusion criteria will be considered as sample.

7.1.6 SAMPLING TECHNIQUE

Convenient sampling technique.

7.1.7 SAMPLE SIZE

The sample size consists of 200 menopausal women between 45-56 years in selected villages at district Budgam, 100 samples will be assigned in the experimental group and 100 in control group.

7.1.8 CRITERIA FOR SELECTION OF SAMPLE

Inclusion criteria

The study includes Women

Who are having menopausal symptoms.

Between the ages 45 – 56 yrs from selected villages of district Budgam.

Who are willing to participate.

Who will be present during the period of data collection.

Exclusion criteria

The study excluded women

Who have undergone Hysterectomy.

Who are receiving hormone replacement therapy.

Who are receiving anticancer therapy.

METHOD OF COLLECTION OF DATA

7.2.1 DATA COLLECTION TOOL

DEVELOPMENT OF THE INSTRUMENT

A structured interview schedule will be developed based on the objectives of the study. Various sources of literature and opinion from the subject experts will be obtained to ascertain the effectiveness and to bring out the correct items in the questionnaire .All these will help in the ultimate development of the tool.

DESCRIPTION OF THE TOOL:

The instrument used in this study consists of two sections which are as follows.

Section A–Description of demographic variables such as Age, Education ,Income, Type of family, Number of children, Medical problems, Treatment taken, Menopause attained.

Section B –It will consist of Wiklund menopausal symptom scale .This scale consists of 10 Menopausal symptoms scale in which the symptoms will be assessed using this scale and the scoring will be given as

Frequently-3

Occasionally-2

Rarely-1 and

Never -0

CONTENT VALIDITY

Content validity is based on the extent to which an instrument adequately represents the universe of content for the concept being measured. The content validity of the tool will be obtained from 10 experts in the field of Medical expert and nursing expert in the field of Obstetrics and Gynaecology and Statistician for relevance, appropriateness, accuracy of the items and for further modifications. Suggestions and opinions of the experts will be considered and changes will be made.

RELIABILITY OF THE TOOL

Reliability is the degree of consistency with which the attributes or variables are measured by an instrument.

Test –retest method will be used to assess the reliability of the instrument. Karl Pearson's Co-effiecient of Correlation will be calculated.

PILOT STUDY

A pilot study is referred to a small-scale preliminary tryout of the method to be used in an actually large study, which acquaints the researcher with problems that can be corrected in proportion for the large research study or is done to provide the researcher with an opportunity to try out the procedure, method, and tools of data collection.

A pilot study will be conducted in Badran, Makhamaa and Adina community areas of Budgam district. Random sampling will be as used to select 20 subjects, 10 in the experimental group and 10 in the control group.

DATA COLLECTION PROCEDURE

The written permission will be obtained from the concerned authority prior to data collection. The study participants will be selected by convenient sampling technique. Formal permission will be obtained from the study participants after explaining the objectives of the study. All the women aged between 45-56 years from the selected village will be screened for items related to menopause and inclusion criteria. In that 200 women aged 45-56 years, who satisfies the selection criteria will be recruited and assigned 100 in the experimental group and 100 in control group .Pre test data will be collected by researcher using Wiklund menopausal symptom scale for both the groups. Experimental group receives intervention of consuming 60 grams of cooked soya bean daily for 6 weeks. No Intervention will be given to control group. Post-test will be conducted by researcher for both the groups using the same menopausal rating scale on the 1st day of 7th week.

METHOD OF DATA ANALYSIS

Demographic variable data will be analyzed by using descriptive statistics like frequency distribution, percentage, mean and standard deviation demographic variables of menopausal symptoms.

Analysis of effectiveness of soybean consumption by comparing pre-test post-test menopausal score will be assessed by using inferential statistics like paired t-test.

"Chi-square" test will be used to find out the association between selected demographic variables and pre-test and post test symptoms.

DOES THE STUDY REQUIRE ANY INVESTIGATION OR INTERVENTION TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

Yes, non invasive procedure. 60 grams of cooked soya bean will be administered for a period of 6 weeks to the women in experimental group and Wiklund menopausal symptom scale will be administered to both experimental and control group to assess the pre-test and post-test severity of menopausal symptoms.

HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION?IN CASE OF 7.3

Permission will be obtained from research committee

Permission will be obtained from the authorities of the community.

Informed consent will be obtained from the participants enrolled before the study

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5.	*a) Does the study require an investigations or interventions to be conducted on patients or humans or animals? If so, please describe briefly.* *Yes the study will be conducted to assess the effectiveness of soya beans on somatic and vasomotor symptoms among menopausal women residing in selected villages at district budgam, KASHMIR* *b) Has ethical clearance been obtained from your institution?* *Yes, informed consent will be obtained from the concerned study subjects and authority.* *Privacy, confidentiality and anonymity will be guarded.* *Scientific objectivity of the study will be maintained with honesty and impartiality*
6.	*Signature of the Candidate: _____* *Place:_____* *Date:_____*
7.	*Remark of the Supervisor : _____*

	_____ *Signature:* _____ *Name:* _____ *Designation:* _____ *Date:* _____ *Place:* _____
8.	*Remark of the Departmental Research Committee:* _____ _____ *Signature:* _____ *Name:* _____ *Designation:* _____ _____ *Signature:* _____ *Name:* _____ *Designation:* _____ _____ *Signature:* _____ *Name:* _____ *Designation:* _____